

## WHAT IS NEW SINCE OUR LAST NEWSLETTER?

#### The Power of One!



In 2017, Canadian resident, Andrea MacGregor, entered her final semester of college. Hating pseudoscience, and despite being in the middle of exams, when she realised that acupuncture was being endorsed by a prestigious Toronto-based children's hospital, she took them on. They listened – and acted.

Following a <u>complaint by FSM</u> to Advertising Standards Canada (ASC), the authority responded that they could not submit it to their Council because the <u>Hospital for Sick Children (Sickkids)</u>, which ranked number two on <u>Canadian top 40 research hospitals</u> for 2016, endorsed acupuncture.

When she heard this, Andrea rose to the challenge and wrote to the hospital, citing the response from ASC, and including <u>informed opinions</u> from 28 experts from 10 countries. *Sickkids* passed her e-mail onto their internal teams (which included the specialists within their Pain Centre) and, after reviewing their research and the information she provided, removed the document titled <u>"acupuncture may help ease chronic pain in young people"</u>. They are now reviewing all their information on complementary and alternative medicine. Well done Andrea!



In a <u>public letter</u>, Andrea raised her concerns about the <u>American College of Physicians</u> (ACP), who recommend acupuncture as a non-pharmacologic treatment. Following the ACP publication, health practitioners world-wide continue to cite this prestigious college as 'evidence' that acupuncture works because it <u>"formally recommends acupuncture for the treatment of back pain"</u>. The response from the ACP was to suggest that Andrea write a comment on the article.

When major health institutions or universities publish pro-CAM information, they are used worldwide by alternative practitioners, their associations, and people with vested interests, as 'evidence'. In Australia, *Flourish Paediatrics* had published a link to the *Sickkids* website to provide information on acupuncture to parents. FSM contacted Flourish and they <u>immediately removed the link</u>.

One person can make a difference!

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Inside this Issue:				
What's New Since Our Last Newsletter? The Power of One!	1	Therapeutic Goods Administration	5	
FSM Executive News		Australian Health Practitioners Regulation Agency	8	
A 'Wikileaks' for Dodgy Pharmacy Practices	2	A Special Report from Edzard Ernst: Pharmacies responsibilities: their vio- lation of healthcare ethics continues.	10	
Social Media News	3	Recent Publications by our Friends	11-12	
Complementary & Alternative Medicine	3			



## **FSM EXECUTIVE NEWS**

Our new website was launched on 18 January! Our thanks to the team, who designed, tested and implemented it.

New features include live updates for Facebook and Twitter and, if you would like to help out financially, donations.

## **Associate Professor Ken Harvey AM!**

The <u>Order of Australia</u> is the principal and most prestigious means of recognising outstanding members of the community at a national level.

Congratulations <u>Dr Ken Harvey AM</u> who was recognised in this year's Queen's Birthday honours "for significant service to community health and the pharmaceutical industry through roles in developing guidelines for the ethical use of antibiotics".



# Seminar: The Advertising of Therapeutic Goods and Services (and its regulation) - 8 September 2017



In March 2016, a <u>seminar on this topic</u> attracted over 100 people to the Sydney University Health Law Centre. One outcome was a decision to hold a follow-up seminar in Melbourne in Sept-Oct 2017.

The <u>2017 seminar</u> is being organised by the Monash Health Law and Society Group and the Monash School of Public Health and Preventative Medicine, in association with Melbourne University Law School, *Choice* (the Australian Consumers' Association), Friends of Science in Medicine (FSM) and the Foundation for Effective Markets

and Governance (FEMAG).

#### **March for Science**

At a time when governments are turning their backs on science, when corporations with vested interests are pouring hundreds of millions of dollars into advertising, and when celebrities and sporting heroes are promoting themselves as 'health experts', vulnerable people, especially children, must be protected.

On 22 April 2017, FSM joined thousands of doctors, scientists and families in Melbourne, Adelaide and Brisbane, when we joined the 'March for Science'.

Over 600 cities around the world participate in this event.

# A 'WIKILEAKS' FOR DODGY PHARMACY PRACTICES

Attention pharmacy worker! To gather stories and data about how Complementary Medicines are being managed in Australian pharmacies today, FSM Pharmacy Facilitator, Ian Carr, has set up an email address: <a href="mailto:pharmacy.cam.leaks@gmail.com">pharmacy.cam.leaks@gmail.com</a>, where you can share your stories.



### International Conference "Revive Health for All"

On 15-16 May, Dr Ken Harvey attended the International Steering Committee (ISC), established to plan, oversee and co-ordinate preparations for an International Conference "Revive Health for All".

The proposed Conference will address the following themes:

- \* The economics of health care;
- Malpractice by health care providers; and
- The role of academics in identifying solutions, facilitating implementation and restructuring medical education.

The Bangladesh Conference, to be held from 10-14 November 2017, is being hosted jointly by Gonoshasthaya Kendra (GK) and its sister institution, Gono Bishwabidyalay (people's university).

## **SOCIAL MEDIA NEWS**



The number of FSM's Facebook and Twitter fans has now passed 8,000.

Health literacy is about how people understand information about health and health care, and how they apply that information to their lives, use it to make decisions and act on it. The <u>Australian Bureau of Statistics</u> Adult Literacy and Life Skills Survey (2006) showed that 60% of Australians "have less than

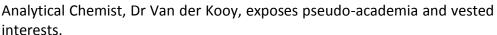
adequate levels of literacy and health literacy, and only 6% of the Australian population has 'high' health literacy levels".

To contribute to health literacy, Dr Pallave Dasari and her social media team have expanding the role of Facebook to add education and information streams which include disease prevention, important health concepts, "did you know?", thanks to science, great moments in health and science, historical figures and abused health concepts.

## COMPLEMENTARY AND ALTERNATIVE MEDICINE

Frank Van der Kooy 's Blog - the view of a previous insider!

Complementary Medicine Australia (CMA). Masters in selling ice to Eskimos, but occasionally, they do slip up and acknowledge it!





#### **Universal Medicine**



In 2014, Professor John Dwyer was interviewed for <u>a state</u> <u>parliamentary inquiry</u> into false and misleading health practices from 'spiritual healing group' Universal Medicine (UM). At the inquiry, Prof Dwyer stated, "There is no doubt whatsoever in my mind that 99.9% of doctors would be horrified to think that [UM-linked doctors] would place patients in the hands of these people ... Could it be that these doctors actually believe?" Dwyer also said that UM patients were subjected to "a whole series of nonsense therapeutic approaches", including "esoteric breast massage".



Other claims included that back and lung massages helped people with lung conditions and that practitioners had "the power to talk to a woman's ovaries and that all illnesses are due to past misdeeds in previous incarnations of your life."



A respiratory physician, who inappropriately referred

patients to other devotees of UM, was reprimanded by the Professional Standards Committee of the Medical Council of <u>New South Wales</u>, because he failed to disclose his involvement in the UM group. The <u>committee also found</u> that a university lecturer associated with UM had made "significant ethical errors and failings in respect of proper professional standards" in treating the woman for a chronic cough for more than two years. The founder of UM is a former bankrupt tennis coach with no medical qualifications.

While little evidence of actual harm was found by the <u>inquiry</u>, "concerns were raised that patients may forego seeking proper medical advice and care".





A call to action to review the regulation of children's vitamins was issued by Associate Professor Ken Harvey, Eliza Li, a biomedical science and business student at Monash University, Dr Rosemary Stanton, a nutritionist and Visiting Fellow at UNSW, and Professor Stuart Dashper, Senior Principal Research Fellow at the University of Melbourne. High in sugar content and with dubious health benefits, they are marketed to children and "promoted as deliciously flavoured and a great way for growing bodies (and fussy eaters) to get the nutrients they need". In reality, they are "unhealthy, poorly regulated and exploitative".

Claiming that they mislead consumers about the benefit of these dietary supplements, the authors requested that the Therapeutic Goods Administration and <u>Food Standards Australia and New Zealand</u> urgently review their regulation.

#### **Complementary Medicine Australia Media Release**

Complementary medicines (CMs) include herbal remedies, vitamins, supplements and homeopathic remedies. A common misconception is that so-called 'natural' products are 'safe' and that, because herbal remedies might have been used for thousands of years, they must work. However, research by the University of Adelaide suggests that people who hold these unfounded beliefs could "unknowingly (be) putting their health at risk".



A Complementary Medicine Australia (CMA) media release, titled "CMA Supports Health Prevention Focus", stated that CM's "have the ability to contribute to a more sustainable, prevention-focused health system in Australia" and that they can "counteract spiralling health care costs through more effective disease prevention and preventable chronic disease management."

Yet another industry-financed study the <u>Frost and Sullivan report</u> (commissioned by ASMI) suggested there could be health benefits (and cost-savings) if complementary medicines were targeted for four disease conditions in certain populations.



The claims included:

- For women aged 50 and over, with osteoporosis or osteopenia, that calcium and vitamin D can prevent fracture. (Refuted in BMJ 2015: "Calcium supplements do not prevent fractures";
- For all Australians aged 55 or over with cardiovascular disease (CVD) use omega-3 fatty acids or a folic acid, B6 and B12 regimen (to reduce subsequent CVD) (Refuted in The JAMA Network 2012: "Omega-3 Fatty Acids and Secondary Prevention of Cardiovascular Disease—Is It Just a Fish Tale?";
- All Australians aged 55 or over with age-related macular degeneration (AMD), use lutein and zeaxanthin (to reduce progression) (Only in high risk-patients when the end=point was defined by late-stage disease - National Eye Institute 2015 "Facts About Age-Related Macular Degeneration"), and
- All Australians aged 20 or over with moderate major depression use St. John's wort (for treatment). (However, this applies only when a specific, standardised extract, proven to be effective in clinical trials, is used. In Australia, no preparation of St. John's Wort has been submitted for clinical evaluation via registration").

No evidence was given by the CMA to support these claims.

#### The Checkout Stories- Fish Oil

Nutritionist and dietician, Dr Rosemary Stanton, appeared in the ABC Checkout program as they investigated "the truth about fish oil supplements", which included supplements promoted for children. The show highlighted a range of false, misleading and exaggerated adverting claims for these supplements, which, in otherwise healthy patients, are no substitute for a healthy diet



and, at best, might provide some benefits for patients with rheumatoid arthritis.

## THERAPEUTIC GOODS ADMINISTRATION



No Penalty Forty of the complaints upheld by the Complaints Resolution Panel are not complied with; the perpetrators suffer no penalties. They are then sent to the delegate of the Secretary (Therapeutic Goods Administration (TGA)) who start a new investigation and then, 12 months or more later, the TGA might write a Regulation 9 letter "ordering" compliance. This is also usually ignored or disputed as there are currently no timely penalties.

## **Options for the Future Regulation of 'Low risk' Products**

FSM understands that the TGA is currently trying to declare homeopathic products to not be 'therapeutic goods' and thus evade its responsibility for them.

FSM supported the submission by Dr Ken Harvey and Dr Prasad Ranaweera, titled "Therapeutic Goods Administration (TGA) Consultation: Options for the future regulation of 'low risk' products". The submission raises concerns that that the regulatory options suggested by the TGA will not protect consumers from the false claims and dangers associated with these products.





The submission also discussed concerns that the consultation document fails to document many long-standing concerns about the supply and promotion of homeopathic products and, in FSM's opinion, fails to provide a viable solution to the problems outlined.

The submission also advocates that the TGA, as a specialist regulator, retain responsibility for regulating these products.

More "needs to be done by the application of mandatory warnings, more stringent post-marketing surveillance and the education of the public and non-registered practitioners (such as many naturopaths) who often inappropriately promote and use these products."

## **Homeopathy**

A complaint to the TGA's Complaints Resolution Panel, relating to advertising claims for the Martin & Pleasance homeopathic remedy, <u>'Restless Legs Relief'</u>, found, based on the advertising claims submitted to the panel, that certain advertising provisions had been contravened. The <u>panels sanctions</u> included "withdrawal of advertising" and "withdrawal of representations". In 2014, the Secretary for the Department of Health had accepted this Martin & Pleasance homeopathic remedy!

FSM wrote to the TGA because that it was inappropriate for the delegate of the Secretary to accept a restricted representation to the effect that the <a href="https://example.com/homeopathic/medicine/Restless Legs">homeopathic medicine/Restless Legs</a> Relief can provide symptomatic relief of restless legs.

## **Non-compliance of Complementary Medicines**

The <u>high rate of non-compliance of complementary medicines</u> continues.

Therapeutic Goods Administration (TGA) compliance activity more than doubled from 212 (2014-15) to 473 (2015-16). Interventions with verified compliance breaches increased from 73% (2014-15) to 80% (2015-16).

Doubling of Compliance Activity

Labelling, advertising and evidence continued to be the major compliance breaches for listed products. More were found to have safety-related issues: zero in (2014-15) compared with 13 (2015-16). In addition, for the same of the same

issues; zero in (2014-15) compared with 13 (2015-16). In addition, for 2015-16, the Therapeutic Goods Advertising Complaint Resolution Panel found 98% of 141 complaints justified (and a 40% non-compliance rate with Panel "requests" for redress).

## **Food and Drugs Administration (USA)**



Chiropractors
& Acupuncturists

In the US, chiropractors and acupuncturists who have lobbied for a bigger role in treating pain have won a preliminary endorsement from federal health officials. The Food and Drugs Administration (FDA) has proposed that doctors learn about acupuncture and chiropractic for pain management.

On 10 May 2017, the FDA invited comments on their "<u>Draft Revisions to the Food and Drug Administration Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids; Availability</u>". The blueprint included a section on "<u>Complementary therapies – e.g., acupuncture, chiropracty</u>" which stated that they should "be knowledgeable about the range of available therapies, when they may be helpful, and when they should be used as part of a multidisciplinary approach to pain management".



As with the TGA, the FDA is responsible for protecting the public health by ensuring the safety and efficacy of therapeutic goods. As such, it should issue a blueprint for proper use of drugs for the management of pain. FSM appreciates that opioids, in particular, pose problems ranging from limited effectiveness to misuse and illicit use.

FSM also appreciates that it is appropriate for the FDA to recommend multidisciplinary pain management, which addresses not only pain but function and the psychological effects of persistent pain. However, FSM remains concerned that the 'Draft Blueprint' mentions acupuncture, both as an alternative treatment and one that should have a place in multidisciplinary pain management. In making this recommendation, the FDA creates an egregious illusion for the public. This endorsement by the FDA implies that acupuncture works. The evidence shows that it does not.





The Cochrane reviews on chiropractic (spinal manipulation therapy), "for chronic low-back pain", concluded that "high quality evidence suggests that there is no clinically relevant difference between SMT and other interventions for reducing pain and improving function in patients with chronic low-back pain." The Cochrane review on chiropractic for "for acute low-back pain" Cochrane concluded that it "is no more effective in participants with acute low-back pain Review than inert interventions, shall swir, or mission some some small swir, or mission sw than inert interventions, sham SMT, or when added to another intervention.

In 2016, the Royal College of General Practitioners asked all their members "to seriously reconsider any support for chiropractic involvement in patient care." A survey by Australian Doctor magazine found that "more than 70% of GPs say they won't refer patients to chiropractors because of concerns over the efficacy and safety of their treatments".

The Australian Health Practitioner Regulation Agency is processing over 600 complaints against chiropractors and has received over 1,000 complaints against acupuncturists.

With the help of Emeritus Professor Nik Bogduk, Australia's premier pain specialist, FSM sent in a submission to the FDA.



**Emeritus Professor** Nik Bogduk

#### Comment

Friends of Science in Medicine (Australia) appreciates that it is appropriate for the FDA to recommend multidisciplinary pain management strategies.

We remain concerned, however, that the Draft Blueprint suggests that acupuncture could have a place in patient care and that it is an effective alternative intervention for pain management.

It is inappropriate for any government organization to endorse a placebo therapy because this will mislead patients, health care providers and decision-makers for health insurance companies.

Our submission (attached) also confirms that spinal manipulation therapy (chiropractic) is no more effective than other manual therapies for back pain.

Patients should be provided with the best scientific evidence, not unsubstantiated unproven claims, to enable them to make informed decisions about their healthcare choices.



## THE AUSTRALIAN HEALTH PRACTITIONER REGULATION AGENCY

#### **Compliance and Monitoring**

An Advertising Compliance Team has now been set up by the Australian Health Practitioner Regulation Agency (AHPRA) to manage complaints about health practitioner advertising. Working with the National Boards, the team is responsible for the triage of all incoming offence complaints, for the assessment of all offence complaints about advertising and for the ongoing management of low and moderate risk advertising. Once a complaint has been assessed as non-compliant, their strategy includes contacting the relevant practitioner, to provide them with an opportunity to check and correct all their advertising, before auditing.

#### **Accreditation Systems Review**

Following the "Independent Review of the National Registration and Accreditation Scheme for health professionals" (NRAS Review), the Australian Health Workforce Ministerial Council (AHWMC) requested that the Australian Health Ministers' Advisory Council (AHMAC) commission an independent review of accreditation systems. Professor Michael Woods was appointed as the Independent Reviewer, with FSM attending meetings in Melbourne and Brisbane.

<u>FSM's submission</u> raised concerns about registered alternative medicine (AltMed) practitioners, accusing the present accreditation system of failing to protect the public through its legitimising poor quality, belief-based, rather than evidence-based, education and on-going training of chiropractors, osteopaths and Chinese medicine/acupuncturists. It also raised concerns about discredited AltMed courses given undeserved credibility by being advertised on Government websites.

FSM allegations included that the training of registered AltMed practitioners was of low quality, was based on pseudoscience, and included invalid diagnostic techniques and that potentially dangerous interventions were included in their ongoing training. FSM also raised concerns that accreditation wastes considerable public funding allocated to universities which teach these unscientific courses and that these courses compromise our universities' reputation within Australia and internationally.

FSM's report included a selection of on-line course notes from an accredited college, relating to treatments for specific conditions, with comments from specialists on their content. These course notes were assessed for conditions including disorders of the eye, ear, nose, mouth & throat, Anxiety, neurasthenia, hysteria, HIV/AIDS obesity and women's physiology.

### **Chiropractic**



FSM submitted reports on 'Retained Neonatal Reflexes' and 'Webster Technique' where chiropractors continue to target the unborn, pregnant women and children.

Retained Neonatal Reflexes (RNR) is a belief-based intervention used by chiropractors as a "revolutionary approach to teaching

children with learning and behavioural difficulties". Parents may be asked to bring their infant to the chiropractor for weekly sessions for up to 3 months.



Based on kinesiology, RNR involves "specific muscle testing and gentle pressure on particular cranial (skull) points, often combined with a specific phase of breathing." The National Health & Medical Research Council 'Natural Therapies Review', included kinesiology. It found "insufficient evidence to reach a conclusion about the effectiveness of specialised kinesiology for any clinical condition". On March 2016, the Chiropractic Board of Australia (CBA) published an Advertising Statement which specifically mentioned that chiropractors must not claim to be able to treat "developmental and behavioural disorders, ADHD and autistic spectrum disorders".

#### **Osteopathy Board of Australia**

In October 2016, FSM submitted a report to AHPRA which documented <u>images from over 200 osteopathy websites</u> targeting babies and children with 'Osteopathy of the Cranial Field (OCF)', a pseudoscience-based intervention which has been rejected by evidence-based osteopaths.



In December 2016, the Advertising Standards Authority (UK) published new advertising guidance for osteopaths.

The <u>guidance</u> related to marketing claims for pregnant women, children and babies and provided examples of what kind of claims can, and can't, be made for these patient groups. The guidance rejected claims for treating conditions specific to pregnant women, children and babies, such as morning sickness or colic. FSM sent these guidelines to the Osteopathy Board of Australia (OBA) and asked that they publish similar guidance. They did not.

In their communiqué to their registrants, the OBA stated "osteopaths should not claim to or provide care for babies and children unless they have the appropriate education, training and competence to do so." No mention was made of OCF, which may still be attracting continuing professional development (CPD) hours for practising osteopaths.

Disturbed by claims for the role of osteopathy in the care of babies, children and pregnant women, FSM wrote to the OBA asking for clarification on osteopathy training that is considered 'appropriate'. We also mentioned that 'visceral manipulation (VM)', which also attracts CPD, and is another common belief-based practice, should not be given any credibility by the Board. On her website, the Chair, OBA, continues to state that she is "proficient in a wide variety of osteopathic techniques which includes osteopathy in the cranial field". In her response to FSM, none of our questions were answered.

#### **Chinese Medicine Board**

FSM documented more than <u>1,000 acupuncture/Chinese medicine</u> websites which are breaching the National Law. These included images from websites from 400+ acupuncture websites promoting the unproven claims originally listed by World Health Organization (WHO) nut now withdrawn by WHO because of their lack of quality evidence, from 300+ acupuncture websites targeting the unborn, from websites claiming that this intervention is either 'safe' and/or 'effective', from websites that target major illnesses and from websites that include testimonials.



## A Special Report from Professor Edzard Ernst

Pharmacists' responsibilities vis a vis alternative medicine: the violation of healthcare ethics continues.

Alternative medicine differs from conventional medicine in numerous ways. One important difference is that patients often opt to try this or that product without consulting any healthcare professional at all. In such cases, the pharmacist might be the ONLY professional who can advise the patient who is about to purchase such a product.

This is why the role of the pharmacist in alternative medicine is crucial, arguably more so than in conventional medicine. And this is why I am banging on about pharmacists who far too often behave like shop-keepers and not like ethical healthcare professionals. A new review addresses these issues and provides relevant information.



Professor Edzard Ernst

Pharmacists from the University of Macau in Macau, China conducted a <u>literature review</u> to extract publications from 2000 to 2015 that related pharmacist to alternative medicine products. 41 publications which reported findings from exploratory studies or discussed pharmacists' responsibilities towards such products were selected for inclusion.

Seven major responsibilities emerged:

- to acknowledge the use of alternative medicine products;
- to be knowledgeable about such products;
- \* to ensure safe use of such products;
- \* to document the use of such products;
- \* to report ADRs related to such products;
- \* to educate about such products;
- to collaborate with other health care professionals in respect to such products.

One point that is not directly covered here is the duty of pharmacists to comply with their own ethical codes. As I have <u>pointed out ad nauseam</u>, this would mean in many instances to not sell alternative medicine products at all, because there is no good evidence to show that they are generating more good than harm and thus are potentially harmful as well as wasteful.

Some pharmacists have realised that there is a problem. Some pharmacists are trying to initiate discussions about these issues within their profession. Some pharmacists are urging to change things. Some pharmacists are well-aware that healthcare ethics are being violated on a daily basis.

All this has been going on now for well over a decade. And has there been any noticeable change? Not as far as I can see!

Perhaps it is time to realise that not merely the sale of bogus medicines by pharmacists is unethical, but so is dragging one's feet in initiating improvements.



### RECENT RELEVANT PUBLICATIONS BY FRIENDS

MJA Insight

Sue Ieraci We must hold charlatans to account

ABC Radio National - Ockham's Razor

Robyn Williams The march of pseudoscience

Croakey

A Current Affair's "ADHD breakthrough": bona fide news or unethical Ken Harvey

advertising?

'The Bitter Pill' - Australasian Science

Benson Riddle Prevention or Pretension?

Rob Morrison Protecting Your Health in a Post-Truth World

The Conversation

Mike Vagg Please don't do your own research on immunisation; you'll get it wrong

**Edzard Ernst** 

Say no to the needle: why acupuncture just isn't worth trying

Acupuncture for back pain: an open letter by a Canadian therapist

Is the Royal College of Nursing promoting quackery?

Alternative medicine for chronic pain: 'State of the Art' review in the BMJ

Brain Dust and other surprises

Acupressure works ... oh no, it doesn't !!!

CAM-use delays cancer diagnosis

Australian Skeptics

Pro-Vaccine measures in 2017 Budget

Homeopathy groups' attack on NHMRC – the missing submission

**Forbes** 

Steven Salzberg An Aspirin A Day Keeps Cancer At Bay, New Study Shows

Science-based Medicine

NCCIH Announces Development of Revolutionary "Needleless" Acupuncture System (Clay Jones)

Is the FDA embracing quackery? A draft proposal recommends that doctors learn about acupuncture and chiropractic for pain management). (David Gorski)

<u>Inoculating – Against Misinformation</u> (Steven Novella)

Protandim Update: New Studies and an FDA Warning Letter (Harriet Hall)

Naturopathic Edumacation: A FAQ (Mark Crislip)

FDA issues warning letter to "holistic" practitioner offering thermography for breast

cancer detection (Jann Bellamy)

The Medical Medium's Thyroid Pseudoscience (Scott Gavura)



Science-based pharmacy (Scott Gavura)

<u>Survey finds one-third of Australian pharmacists are recommending unproven therapies</u>

Respectful Insolence (David Gorski)

Acupuncturists mistake insufficient rigor for bias against them

The New York Times publishes fake news false hope in the form of a credulous account of dubious alternative medicine testimonials

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